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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,484	09/27/2004	Yasuaki Ito	62236(46342)	5324

21874 7590 03/13/2006

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,484	ITO ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 9-10, 12 and 42, in so far as they are drawn to polypeptide of SEQ ID NO: 2, encoding polynucleotide, and first method of using the polypeptide as a diagnostic agent.

Group II, claim(s) 1-6, 9-10, 12 and 42, in so far as they are drawn to polypeptide of SEQ ID NO: 4, encoding polynucleotide, and first method of using the polypeptide as a diagnostic agent.

Group III, claim(s) 7-8 and 44-45, in so far as they are drawn to antibodies to a polypeptide of SEQ ID NO: 2.

Group IV, claim(s) 7-8 and 44-45, in so far as they are drawn to antibodies to a polypeptide of SEQ ID NO: 4.

Group V, claim(s) 11 and 18, in so far as they are drawn to a method of screening a compound that changes the binding properties of polypeptide of SEQ ID NO: 2.

Group VI, claim(s) 11 and 18, in so far as they are drawn to a method of screening a compound that changes the binding properties of polypeptide of SEQ ID NO: 4.

Group VII, claim(s) 13, 19-20 and 23-24, in so far as they are drawn to a compound that changes the binding properties of polypeptide of SEQ ID NO: 2.

Group VIII, claim(s) 13, 16-17, 19-20 and 23-24, in so far as they are drawn to a compound that changes the binding properties of polypeptide of SEQ ID NO: 4.

Group IX, claim(s) 14 and 21, in so far as they are drawn to a method of screening an agonist or antagonist of polypeptide of SEQ ID NO: 2.

Group X, claim(s) 14 and 21, in so far as they are drawn to a method of screening an agonist or antagonist of polypeptide of SEQ ID NO: 4.

Group XI, claim(s) 15 and 22, in so far as they are drawn to a kit for screening an agonist or antagonist of polypeptide of SEQ ID NO: 2.

Group XII, claim(s) 15 and 22, in so far as they are drawn to a kit for screening an agonist or antagonist of polypeptide of SEQ ID NO: 4.

Group XIII, claim(s) 25, in so far as it is drawn to an agonist to a polypeptide of SEQ ID NO: 2.

Group XIV, claim(s) 25, in so far as it is drawn to an agonist to a polypeptide of SEQ ID NO: 4.

Group XV, claim(s) 26, in so far as it is drawn to an antagonist to a polypeptide of SEQ ID NO: 2.

Group XVI, claim(s) 26, in so far as it is drawn to an antagonist to a polypeptide of SEQ ID NO: 4.

Group XVII, claim(s) 27, in so far as it is drawn to a method of screening a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 2.

Group XVIII, claim(s) 27, in so far as it is drawn to a method of screening a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 4.

Group XIX, claim(s) 28, in so far as it is drawn to a kit for screening a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 2.

Group XX, claim(s) 28, in so far as it is drawn to a kit for screening a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 4.

Group XXI, claim(s) 29-32, in so far as they are drawn to a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 2.

Group XXII, claim(s) 29-32, in so far as they are drawn to a compound having an action of changing the expression level of a polypeptide of SEQ ID NO: 4.

Group XXIII, claim(s) 33, in so far as it is drawn to a method of screening an agonist of a polypeptide of SEQ ID NO: 2.

Group XXIV, claim(s) 33, in so far as it is drawn to a method of screening an agonist of a polypeptide of SEQ ID NO: 4.

Group XXV, claim(s) 34-39, in so far as they are drawn to an agent for fortifying the signal transduction of a polypeptide of SEQ ID NO: 2.

Group XXVI, claim(s) 34-39, in so far as they are drawn to an agent for fortifying the signal transduction of a polypeptide of SEQ ID NO: 4.

Group XXVII, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of a polypeptide of SEQ ID NO: 2.

Group XXVIII, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of a polynucleotide encoding polypeptide of SEQ ID NO: 2.

Group XXIX, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of an agonist to a polypeptide of SEQ ID NO: 2.

Group XXX, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of a polypeptide of SEQ ID NO: 4.

Group XXXI, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of a polynucleotide encoding polypeptide of SEQ ID NO: 4.

Group XXXII, claim(s) 40, in so far as it is drawn to a method for treating anxiety by administration of an agonist to a polypeptide of SEQ ID NO: 4.

Group XXXIII, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of an antibody to a polypeptide of SEQ ID NO: 2.

Group XXXIV, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of a polynucleotide encoding polypeptide of SEQ ID NO: 2.

Group XXXV, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of an antagonist to a polypeptide of SEQ ID NO: 2.

Group XXXVI, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of an antibody to a polypeptide of SEQ ID NO: 4.

Group XXXVII, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of a polynucleotide encoding polypeptide of SEQ ID NO: 4.

Group XXXVIII, claim(s) 41, in so far as it is drawn to a method for treating ataxia by administration of an antagonist to a polypeptide of SEQ ID NO: 4.

Group XXXIX, claim(s) 42-43, in so far as they are drawn to use of a polypeptide of SEQ ID NO: 2.

Group XL, claim(s) 42-43, in so far as they are drawn to use of a polynucleotide encoding polypeptide of SEQ ID NO: 2.

Group XLI, claim(s) 42-43, in so far as they are drawn to use of an agonist of a polypeptide of SEQ ID NO: 2.

Group XLII, claim(s) 42-43, in so far as they are drawn to use of a polypeptide of SEQ ID NO: 4.

Group XLIII, claim(s) 42-43, in so far as they are drawn to use of a polynucleotide encoding a polypeptide of SEQ ID NO: 4.

Group XLIV, claim(s) 42-43, in so far as they are drawn to use of an agonist to a polypeptide of SEQ ID NO: 4.

2. The inventions listed as Groups I to XLIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As such, pursuant to 37 C.F.R. § 1.475 (b), the ISA/US considers that when an international or a national stage application containing claims to different categories of invention unity of invention exists if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Accordingly, the main invention (Group I) comprises the first recited product, a protein of SEQ ID NO: 2, encoding polynucleotide and a first method of use of the protein as a diagnostic agent. Pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that any feature which is the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. As such, the inventions recited in Groups II to XLIV are directed to structurally and functionally different compounds and methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these compounds would be used together. Furthermore, the recited methods are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Moreover, the methodology and materials necessary for practicing methods of diagnosis and treatment of diseases differ significantly for each of the materials.. For these reasons the Inventions II to XLIV are patentably distinct.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate

in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner

Art Unit 1649

March 1, 2006